FEE

DATE OUT: **01 / NOVEMBER / 2011**

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP [ ]**
DP BARCODE No.: DP385571 **EPA File Symbol No.:** 11556-RLU
PRODUCT NAME: Flumethrin Technical
COMPANY: Bayer Healthcare LLC.
FOOD USE [ ] INTEGRATED FORMULATION [X]
PCC: 036007 **Decision No.** 440305
ACTION CODE: R110.0

FROM: Hari Mukhoty, DVM, PhD
Product Chemistry Team
Technical Review Branch / RD (7505P)

11/02/11

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INTRODUCTION:

The Registrant has submitted a basic CSF (dated: 11/15/2008) for a proposed TGAI/MUP, and has also proposed a product specific label for registration of the aforesaid product under EPA File symbol 11556-RLU. The product chemistry data have been submitted under MRIDs: 482402-01 and -02.

The primary review of the product chemistry data was performed by a contractor, Summitec Corporation, Tennessee (DER document is attached at the last page of this review) and TRB is conducting the secondary review.

The aforesaid MUP is manufactured by Bayer CropScience Limited in India for Bayer Healthcare, Kansas in USA.

The registrant in their application for registration indicates that this proposed MUP is intended to be formulated into end-use products to be used on pets i.e., for non-food uses with indoor applications.

TRB has been requested to evaluate the product chemistry data required for the registration of the proposed MUP.

SUMMARY OF FINDINGS:

1. The proposed TGAI/MUP contains the active ingredient: Flumethrin (96.2%).

2. The overall mean of the active ingredient from the five batch analysis is 97.24% [MRID: 482402-01, Page 24].

3. The proposed nominal concentration of the active ingredient in the MUP is 96.2%. The nominal concentration of the active ingredient matches with the label claim. This is in compliance with PR Notice 91-2. The registrant proposed different (not standard) certified limits for the active ingredients and impurities which comply with 40 CFR § 158.175 (c) (1). The registrant justified their choice of proposed certified limits on the basis of their expected production variability.

4. The CSF of the proposed TGAI/MUP is filled out completely and correctly. This CSF has been reviewed by I.I.A. Branch on 10/28/2011 and they have concluded that it contains active ingredient and impurities only.

5. The product chemistry data submitted for Group A corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.320, 158.325, 158.330, 158.340, and 158.350 respectively for the proposed formulation [MRID: 482402-01).

6. The active ingredient, some of the associated impurities and the ratio of the Z-isomers were quantified by normal phase HPLC method using UV detector set at 268 nm through external standard. Relative diastereomeric ratio between trans-Z1 and trans-Z2 isomers were determined to be: 58.73% / 41.28% [MRID: 482402-01, see also pages 34-35 of this review]. The label claims that Trans Z1 / Trans Z2 ratio: max 66% Trans Z-1 and min 34% Trans Z-2.

Some impurities were also identified by GC.

Other impurities were determined by a GC method with FID detector and internal standard calibration.

For the determination of the [redacted]. The [redacted]

Similar analytical techniques can also be applied for Enforcement Analytical Method.

7. Product chemistry Group A and Group B data, with the exception of with the exception of Storage stability (830.6317) and Corrosion characteristics are satisfied (830.6320) [MRIDs: 484402-01 and -02].

8. The registrant did not comment regarding the toxicological significance of the associated impurities present in the proposed TGAI/MUP.

CONCLUSIONS:

1. TRB has reviewed the CSF for the proposed TGAI/MUP (dated: 11/15/2008) and has found it to be acceptable.

2. Product chemistry data requirements for Group A and Group B, with the exception of Storage stability (830.6317) and Corrosion characteristics (830.6320) are satisfied and acceptable.

3. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the PM team.

DP BARCODE No.: 385571 **EPA File Symbol No.:** 11556-RLU **PRODUCT NAME:** Flumethrin Technical

PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Group A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (same as in Product CSF dated 11/15/2008)	A	482402-01
830.1600. Beginning Materials	A	"
830.1620. Production process	A	"
830.1650. Formulation process	NA	
830.1670. Discussion of Impurities	A	"
830.1700. Preliminary Analysis	A	"
830.1750. Certified Limits	A	"
830.1800. Enforcement Analytical Method	A	"

A = Acceptable NA = Not Applicable

Group – B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	A	Amber	482402-02
830.6303. Physical State	A	Solid	"
830.6304. Odor	A	No distinguishable odor	"
830.6313. Stability to normal and elevated temp, metals and metal ions	A	Stable when exposed to normal & elevated temp and metals & metal ions	"
830-6314. Oxidation/Reduction action – Chemical incompatibility	A	Oxidized by both weak and strong oxidizing agents.	"
830.6315. Flammability	A	Not a combustible liquid.	"
830.6316. Explodability	A	Thermally stable at ambient and elevated temperature ranging from 25°C to 270° C. No exothermic reaction occurred until 298°C	"
830.6317. Storage stability	G		"
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	G		"
830.7200. Melting point	A	156.4°C	"
830.7220. Boiling point	A	Goes from glass like solid state to a liquid state without going through a melting stage. No boiling point was observed in DSC scan.	"

830.7050. UV/visible light absorption	A	The max absolute absorption occurs at 268 nm, and remains constant in buffer solutions.	"
830.7100 Viscosity	A	NA	"
830.7370. Dissociation Constant	A	Does not contain any acidic protons or basic centers, no dissociation occurs in water.	"
830.7550. Partition Coefficient	A	Log Kow = 7.52 estimated using linear regression from data obtained by LC	"
830.7950. Vapor Pressure	A	Less than 2.442 x 10-5 Pa @ 24.8°C determined by Gas –saturation method	"
830.7840. Solubility	A	@ 20°C In water = 0.06 mg/L pH 4 = 0.046 mg/L pH8 = 0.47 " pH9 =0.33 "	"
830.7000. pH	A	4.51	"
830.7300. Density	A	1.383 g/ml @ 20 C°	"

Explanations: A = Acceptable, NA = Not applicable, G = Data gap